REMARKS

In response to the above Office Action, claims 1 and 4 have been amended to limit the thiazole compound to the compound of claims 2 and 5 and a salt thereof and claims 2 and 5 have been cancelled. Claims 1 and 4 have also been amended to recite that the amount of the thiazole compound or a salt thereof in the enema preparation is one tenth as much as the amount used with oral administration. Support for this amendment can be found on page 8, line 27 to page 9, line 6.

In view of the amendments to the claims, it is believed the objections and rejections of the claims under 37 C.F.R. 1.75(c), and under 35 U.S.C. §101 and § 112 are now moot.

New claims 8-13 have been added to round out the scope of protection. Support for claims 8-11 can be found on page 6, line 22 to page 7, line 1; for claim 12 on page 7, line 20; and for claim 13 on page 8, line 2.

In the Office Action the Examiner provisionally rejected claims 1-3 for obviousness-type double patenting over claims 1-6 of application No. 10/424,904 and claims 4-7 for obviousness-type double patenting over U.S. Patent No. 6,291,487.

The present invention, as now set forth in claims 1 and 4, can reduce the amount of the claimed thiazole compound or a salt thereof to such an extent that the skilled artisan could not conceive from commercially available drugs, it taking the form of an enema preparation. Accordingly, it is believed that the present invention is distinguishable from and patentably independent from the claims of U.S. Patent No. 6,291,487 and copending Application No. 10/424,904. Their withdrawal as a ground of rejection for obviousness-type double patenting is therefore requested.

The Examiner also rejected claims 1-7 under 35 U.S.C. §102(b) for being anticipated by Banan et al. (hereafter Banan). The claims were also rejected under 35 U.S.C. §103(a) for being obvious over U.S. Patent No. 6,291,487 to Chihiro et al. (hereafter Chihiro).

Banan describes: "Our studies suggest that the most appropriate route for administering the OPC compounds (corresponding to the compound of claims 1 and 4) is a combined systemic and local (enema) administration where these drugs can scavenge oxidants associated with both the basolateral aspect of epithelial cells (produced by PMN) and the apical aspect of cell monolayers (produced by the luminal factors, bacteria and/or immunocytes). However, it is possible that either a systemic (oral) or local (enema) administration of OPC compounds could effectively scavenge oxidants produced at the basolateral or apical side of epithelial cell monolayers. Further studies will be required in patients to ascertain the effectiveness of these possible routes (page 296, right column, lines 6 to 18)"

The descriptions, however, just refer to possible administration routes for the OPC compound. The specification of the present application describes that a significant disorder-suppressing effect was observed when an amount one tenth as much as that used with oral administration of the pharmacologically active ingredient of the present application was intrarectally administered. Therefore, the less amount of the agent could significantly suppress undesirable adverse effects (page 8, lines 27 to page 9, line 6 of the original specification).

Banan et al. does not mention this at all. Therefore, since this feature is now set forth in claims 1 and 4, it is submitted that the present invention is not anticipated by Banan.

With regard to Chihiro, the specification of the present application at pages 10 to 13, especially page 12, line 20 to page 13, line 4, describes that a significant disorder-suppressing effect was observed when an amount one tenth as much as that orally administered of the pharmacologically active ingredient of the present application was intrarectally administered. Therefore, the less amount of the agent could significantly suppress undesirable adverse effects (page 8, lines 27 to page 9, line 6 of the specification).

Generally, high therapeutic effects are expected since an active ingredient can be directly injected to an affected part where a treatment is needed when an agent is rectally administered. However, when mesalazine, prednisolone, methylprednisolone, dexamethasone, betamethasone and hydrocortisone, known as pharmacologically active ingredients of drugs which are commercially available for treating regional enteritis or ulcerative colitis, are administered in the dosage form of enema preparations, the improvement in therapeutic effects is only 1.2 to 2.3 times as potent as in the dosage form of oral preparations or injections (page 2, line 25 to page 3, line 6 of the original application).

The present invention significantly reduces the amount of the agent to such an extent that one skilled in the art could not conceive from commercially available drugs, it taking the form of enema preparation. This is not disclosed or suggested at all in Chihiro.

Consequently, it is submitted that the present claims 1 and 4 and claims 8-13 dependent therefrom cannot be considered obvious over Chihiro.

It is believed claims 1, 4, and 8-13 are in condition for allowance.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Attachments: **Replacement Abstract**

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